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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,069	03/24/2006	Shinichiro Kitahara	Q91145	9083

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,069	KITAHARA ET AL.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-14* is/are pending in the application.

4a) Of the above claim(s) *7 in-part, 11 in-part and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, 7 in-part, 8,9, 11 in-part and 12-13* is/are rejected.

7)☒ Claim(s) *7 in part and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/2006,10/28/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment to the claims filed 3/16/2007 has been entered into the record. Claims 2 and 3 have been canceled. Claims 1 and 4-14 are pending in the application.

Claims 1, 4-6, 7 in-part, 8-10, 11 in-part and 12-13 and species polystyrene polymer material and phenolic resin are currently under examination in response to the restriction requirement of 12/18/2006 (see below).

Election/Restrictions

Applicant(s) election without traverse of Group I claims 1, 4-6, 7 in-part, 8-10, 11 in-part and 12-13 and species polystyrene polymer material and phenolic resin in the reply filed 3/16/2007 is acknowledged.

Claims 7 in-part, 11 in-part and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and specie there being no allowable generic or linking claim.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings are objected to because the specification does not disclose any figure legend for Fig.1 fully describing the parts of Fig.1 annotated by numbers. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as " amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either " Replacement Sheet" or " New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant(s) are specifically cautioned against adding new matter in response to this request.

Specification

The disclosure is objected to because of the following informalities:

The specification does not contain a figure legend for figure 1. The specification on p.22 describes Fig.1 as a schematic cross-sectional view, which shows an example of the instrument for inducing a cytokine of the present invention. This description is insufficient as Fig.1 contains numbers pointing to different parts of said instrument without any explanation of what the parts are.

Applicant(s) are specifically cautioned against adding description of parts not described elsewhere in the specification. The amendatory textual material must find basis in the specification as originally filed.

Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed 10/28/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a legible copy of: each foreign patent and each publication or that portion which caused it to be listed is absent.

All references have been lined through and the information disclosure statement has been placed in the application file, but the information referred to therein has not been considered as to the merits.

The information disclosure statement filed 3/24/2006 has been considered. An initialed copy is enclosed. Documents lined through fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. A partial translation (as indicated on the IDS) of the Hayashi reference is not available. Applicant(s) are requested to resubmit said partial translation.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1).

Claim Objections

Claim 7 in-part is objected to because of the following informalities: *Comprises* is spelled incorrectly in the claim. Appropriate correction is required.

Claim 10 is objected to as being dependent on a rejected claim.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 6, 7 in-part, 12 and 13 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9,10,11 and 12 of copending Application No. 10/555,068. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Nonstatutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the " right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,4,5,6,7 in-part and 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-12 copending Application No. 10/555,069. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or

the hemolytic streptococcus-origin component, wherein the water insoluble carrier comprises a polymer material, wherein said polymer material is porous, wherein said polymer material is polystyrene based.

The claims of Application # 10/555,069 (as set forth supra) teach a cytokine inducing instrument characterized as containing a cytokine inducing agent and a water insoluble induction enhancer wherein the cytokine inducing material as hemolytic streptococcus and/or a substance derived from hemolytic streptococcus. The 10/555,069 claims teach a cytokine inducing instrument a container and teach a polymeric water insoluble porous polymer material such as polystyrene.

Thus, claims 1,4,5,6,7 in-part and 12-13 of the instant application are obvious over claims 8-12 of application # 10/555,069. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1,4,5,6,7 in-part and 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 6, 9,12, 13 of copending Application No. 10/493,444. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The instant claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component, wherein the water insoluble carrier comprises a polymer material, wherein said polymer material is porous, wherein said polymer material is polystyrene based.

Application # 10/493,444 teach a cytokine inducing material characterized as containing a cytokine inducing agent and a water insoluble induction enhancer. Claim 9

of the 10/493,444 teaches the cytokine inducing material as hemolytic streptococcal or a substance derived from hemolytic streptococcal. Claims 12 and 14 (of 10/493,444) teach a cytokine inducing material accommodated in a container and claim 6 teaches a polymeric water insoluble porous enhancer such as polystyrene and teach that the cytokine inducing material is fixed to said induction container.

Thus, claims 1,4,5,6,7 in-part and 12-13 of the instant application are obvious over claims 2, 6, 9,12, 13 of application # 10/493,444.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1, 4-6, 7 in-part, 8-10, 11 in-part and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component.

The dictionary definition of instrument is a tool or mechanical device especially one used for precision work in science, medicine or technology or a means of doing something, that is something used as a means of achieving a desired result or

accomplishing a particular purpose (see definition in MSN Encarta Online Dictionary provided).

The specification does not provide a definition for instrument and thus it is not clear in the specification or claims whether the claims are directed to a tool or mechanical device for inducing a cytokine or simply a means of achieving a desired result. Applicant(s) are respectfully requested to clarify the word *instrument* in the claims as it pertains to the instant invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4,5,6,7 in-part, 8, 9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaieda et al. JP 61277628, 8/12/1986 (English abstract and translation provided).

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine; a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer

material, wherein the polymer material is a porous polymer material, wherein the polymer material comprises polystyrene, wherein the water-insoluble carrier comprises a carbon material, wherein the carbon material is an active carbon. The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell, which can produce a cytokine wherein the cell; which can produce a cytokine, is a cell, derived from blood or a blood constituent.

Kaieda et al teach a lymphocyte stimulation material comprising hemolytic streptococcus component (OK-432) and a water insoluble carrier porous polymer such as, glass, sepharose, porous carbon material (activated carbon e.g. charcoal) or a polymer material such as polystyrene (abstract, p.5 first and second paragraph). Kaieda et al teach that said streptococcus component can be fixed by covalent bonding to said carrier (p. 5 last bridging paragraph). As to claims 12 and 13 which recite *the instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent,* such recitation is an intended use of said instrument which is not seen to limit the structure of said instrument (M.P.E.P. § 2114). Thus, the claims are drawn to said instrument and not the use of the instrument. Kaieda teach said lymphocyte stimulation material in a container (last bridging paragraph of p.8 to p.9).

Claims 1, 4,5,6, 8, 9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Tabata et al in Progress in Lymphology: Proceedings of the XIIth International Congress of Lymphology, 1990, (p. 611-612), edited by Nishi et al.

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic

streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the water-insoluble carrier comprises a carbon material, wherein the carbon material is an active carbon. The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Tabata et al teach a composition comprising hemolytic streptococcus component (OK-432) and a water insoluble carrier polymer such as, porous carbon material (activated carbon particles). Tabata et al teach that said streptococcus component is adsorbed to said carrier (see title). Tabata et al teach injection of said composition in rabbits (see materials and methods). Injections are administered via a syringe, thus Tabata et al inherently teach said composition in a syringe container.

As to claims 12 and 13 which recite *the instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent,* such recitation is an intended use of said instrument which do not limit the structure of said instrument (M.P.E.P. § 2114) . Thus, the claims are drawn to said instrument and not the use of the instrument.

Claims 1, 4,5,6, 7 in-part and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Antoon et al. (Applied and Environmental Microbiology, 1985).
The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component and the water-insoluble carrier wherein the hemolytic

streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the polymer material comprises polystyrene, The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Antoon et al. teach a container (page 1271, Figure 1) that holds liquid that comprises *Streptococcus sanguis* (S. Sanguis, a hemolytic streptococcus) adhered to several polymers by physical adsorption (page 1270, abstract). These polymers include the water-insoluble polymer, polystyrene (page 1271, Table 1). As to claims 12 and 13 which recite *the instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent,* such recitation is an intended use of said instrument which do not limit the structure of said instrument (M.P.E.P. § 2114). Thus, the claims are drawn to said instrument and not the use of the instrument. Since the instant product and that of Antoon are the same, the product of Antoon et al will also induce a cytokine.

Claims 1, 4,5,6, 8 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakamoto et al, US 4,536,387, 1985.

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on

the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the water-insoluble carrier comprises a carbon material. The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Sakamoto et al teach an anti-cancer device comprising a hemolytic streptococcus component, OK432 (column 4 line 18) which can be fixed by bonding adsorption or encapsulation by water insoluble carrier such as porous synthetic polymers and porous polymers such as cellulose (column 3 lines 18-25). Cellulose comprises carbon. Sakamoto teach said device in a container e.g. a catheter or a needle (injection). Column 7 lines 46-57 and column 8 line 3-7).

As claims 12 and 13 which recite *the instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent,* such recitation is an intended use of said instrument which do not limit the structure of said instrument (M.P.E.P. § 2114). Thus, the claims are drawn to said instrument and not the use of the instrument. Since the instant product and that of Sakamoto are the same, the product of Sakamoto et al will also induce a cytokine.

Claims 1, 4,5,6, 8, 9 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Okano et al. Conference selected papers: Recent Advances in Management of Digestive cancers-International Symposium, March 1993, p.388-390

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic

streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the water-insoluble carrier comprises a carbon material, wherein the carbon material is an active carbon. The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Okano et al teach a composition comprising hemolytic streptococcus component (OK-432) adsorbed onto a water insoluble carrier e.g. a porous polymer material such as, activated carbon (see abstract). As claims 12 and 13 which recite *the instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent,* such recitation is an intended use of said instrument which do not limit the structure of said instrument(M.P.E.P. § 2114). Thus, the claims are drawn to said instrument and not the use of the instrument. Okano et al teach said composition is injected into mice (see abstract). Injections are administered via a syringe, thus Okano et al inherently teach said composition in a syringe container. Since the instant product and that of Okano are the same, the product of Okano et al will also induce a cytokine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4,5,6,7 in-part, 8, 9,11 in part and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaieda et al. JP 61277628, 8/12/1986 (English abstract and translation provided) in view of Oya et al. Carbon vol. 34, p.53-57, 1996 and Yamamoto et al. Carbon vol. 39, p. 1643-1651, 2001.

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the polymer material comprises polystyrene, wherein the water-insoluble carrier comprises

a carbon material, wherein the carbon material is an active carbon, wherein the active carbon is obtained from phenolic resin The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Kaieda et al is set forth supra. Kaieda et al does not teach activated carbon obtained from phenolic resin.

Oya et al teach the preparation of active carbon fiber from phenolic resin used as antibacterial agent against bacteria (see abstract and p. 53 under preparations).

Yamamoto et al teach that carbon materials have excellent affinity with microorganisms and that bacteria adsorbs on the surface of carbon materials.

It would have been prima facie obvious to one of skill in the art at the time of the invention to use activated carbon obtained from phenolic resin in the composition of Kaieda et al because Oya et al teach the preparation of active carbon fiber from phenolic resin used as an antibacterial agent against bacteria and Yamamoto teach that carbon materials have excellent affinity with microorganisms and that bacteria adsorbs on the surface of carbon materials.

Claims 1, 4,5,6, 8, 9,11 in-part and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabata et al in Progress in Lymphology: Proceedings of the XIIth International Congress of Lymphology, 1990, (p. 611-612), edited by Nishi et al in view of Oya et al. Carbon vol. 34, p.53-57, 1996 and Yamamoto et al. Carbon vol. 39, p. 1643-1651, 2001.

An instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which
induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic

streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the water-insoluble carrier comprises a carbon material, wherein the carbon material is an active carbon, wherein the active carbon is obtained from phenolic resin. The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Tabata et al is set forth supra. Tabata et al does not teach active carbon obtained from phenolic resin.

Oya et al teach the preparation of active carbon fiber from phenolic resin used as antibacterial agent against bacteria (see abstract and p. 53 under preparations).

Yamamoto et al teach that carbon materials have excellent affinity with microorganisms and that bacteria adsorbs on the surface of carbon materials.

It would have been prima facie obvious to one of skill in the art at the time of the invention to use activated carbon obtained from phenolic resin in the composition of Tabata et al because Oya et al teach the preparation of active carbon fiber from phenolic resin used as an antibacterial agent against bacteria and Yamamoto teach that carbon materials have excellent affinity with microorganisms and that bacteria adsorbs on the surface of carbon materials.

Claims 1, 4,5,6, 8, 9, 11 in-part and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okano et al. Conference selected papers: Recent Advances in Management of Digestive cancers-International Symposium, March 1993, p.388-390 in view of Oya et al. Carbon vol. 34, p.53-57, 1996 and Yamamoto et al. Carbon vol. 39, p. 1643-1651, 2001.

The claims are drawn to an instrument for inducing a cytokine, which comprises hemolytic streptococcus and/or a hemolytic streptococcus-origin component which induces a cytokine, a water-insoluble carrier having an effect for enhancing induction of a cytokine, and a container comprising the hemolytic streptococcus and/or the hemolytic streptococcus-origin component and the water-insoluble carrier wherein the hemolytic streptococcus and/or the hemolytic streptococcus-origin component have been fixed on the water-insoluble carrier, wherein the water-insoluble carrier comprises a polymer material, wherein the polymer material is a porous polymer material, wherein the water-insoluble carrier comprises a carbon material, wherein the carbon material is an active carbon, wherein the active carbon is obtained from phenolic resin. The instrument for inducing a cytokine which is used for the induction of a cytokine production in a cell which can produce a cytokine wherein the cell which can produce a cytokine is a cell derived from blood or a blood constituent.

Okano et al is set forth supra. Tabata et al does not teach active carbon obtained from phenolic resin.

Oya et al teach the preparation of active carbon fiber from phenolic resin used as antibacterial agent against bacteria (see abstract and p. 53 under preparations).

Yamamoto et al teach that carbon materials have excellent affinity with microorganisms and that bacteria adsorbs on the surface of carbon materials.

It would have been prima facie obvious to one of skill in the art at the time of the invention to use activated carbon obtained from phenolic resin in the composition of Okano et al because Oya et al teach the preparation of active carbon fiber from phenolic resin used as an antibacterial agent against bacteria and Yamamoto teach that carbon materials have excellent affinity with microorganisms and that bacteria adsorbs on the surface of carbon materials.

Status of the Claims

Claims 1, 4-6, 7 in-part, 8,9, 11 in-part and 12-13 are rejected. Claim 7 in part and 10 are objected to.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner' s Supervisory Examiner Jeffery Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Oluwatosin Ogunbiyi
Examiner
Art Unit 1645

PATRICIA A. DUFFY
PRIMARY EXAMINER